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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,279	03/18/2004	M. David Butts	480062004300	5654

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 06/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,279

Applicant(s)

BUTTS ET AL.

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 26-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/16/05, 6/14/04, 6/21/04, 11/9/04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species III, claims 1-3, 5-25, in the reply filed on 2/06/2006 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 5, 10, 12, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al (US 6099519). Olsen discloses a catheter sleeve connecting assembly comprising a body 18 having a cannula 14 and a tail 48, the cannula being sized to slidably receive a catheter 10 and tail being sized to slidably receive a tube (Col. 2, lines 29-31). The device further comprises a securement device 20, separably attachably to body, having mating portions 66, 68 that secure catheter to the body by locking together (Col. 2, lines 57-59). See Fig. 2. The body further comprises a ribbed region 54, 56 that allow for a tight seal between the catheter receiver and the catheter (Col. 2, line 66 – Col. 3, line 4). The mating portions of the securement device are attached by a living hinge 42 (Col. 2, lines 36-38).

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4. Claims 1, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters (US 6508807). Peters discloses a coupling for a medical cannula comprising a body with a cannula and a tail 6, a securement device 30 with mating portions 48, 49, wherein the body has a head 44 positioned at the distal end and the cannula extends from the head. See Figs. 4 and 5. The mating portions are separably attached to the body and comprise cut-away portions to receive head, wherein the head is inherently slightly smaller than the cut-away portions as it is sized to fit inside the cut-away portions.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 2, 3, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Clark et al (US 4723948). Claim 2 differs from Olsen in calling for the body and the securement device to be unitary. Clark teaches a catheter attachment system wherein the body and the securement device are unitary which minimizes local stresses on the catheter in the region of the connection (Col. 2, lines 41-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Olsen so that the body and the securement device are unitary as taught by Clark to minimize local stresses on the catheter in the region of the connection.

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7. Claim 7 differs from Olsen in calling for the tail to have a barbed end. Clark teaches the use of a barbed end on the end of the cannula being inserted to function as a guide to center the cannula in the lumen and to engage the inner surface of the lumen (Col. 3, lines 15-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to make the end of the tail barbed as taught by Clark to guide the tail into the tube and to engage the inner wall of the tube.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. Olsen meets the claim limitations as described above, but fails to include the cannula made of metal. At the time the invention was made, it would have been an obvious matter of design choice to make the cannula of metal. Applicant has not disclosed that having a metal cannula serves an advantage or particular purpose or solves a stated problem. Furthermore, one of ordinary skill in the art would expect Olsen's device and applicant's invention to perform the same function equally as well with a variety of materials well known in the art. Therefore, it would have been prima facie obvious to modify Olsen to have a metal cannula because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art of Olsen.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Fonger et al (US 5190528). Claim 8 differs from Olsen in calling for the open end of the cannula to be rounded. Fonger teaches a cannula with a rounded distal end to prevent scraping within the catheter when the cannula is inserted into the catheter (Col. 3, lines 44-46). Therefore,

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it would have been obvious to one of ordinary skill in the art at the time of invention to modify the cannula of Olsen to have a rounded open end as taught by Fonger so that the cannula with not scrape within the catheter when it is inserted.

10. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Gross et al (US 4432759). Claim 9 differs from Olsen in calling for the open end of the cannula to have a beveled edge. Gross teaches a connecting device comprising a beveled tip to ease insertion. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Olsen to have a beveled tip as taught by Gross to ease insertion.

11. Claims 14- 16, 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Wilson et al (WO 02/058776) in further view of Brimhall et al (US 2003/0065288). Claims 14 and 21-25 differ from Olsen in calling for the connector to comprise a winged covering apparatus. Wilson teaches a catheter having a connection cover 34 that prevents inadvertent separation of the catheter tube from the connector after insertion of the catheter into the patient (Page 8, lines 6-8). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Olsen to include a cover as taught by Wilson to prevent inadvertent separation of the catheter tube from the connector after insertion of the catheter.

12. Claim 14 further differs from the teachings of Olsen in view of Wilson in calling for the covering to comprise wings. Claim 15 further calls for the winged covering apparatus to be made of silicone. Brimhall teaches the use of wings to facilitate taping or suturing of the catheter to the patient's skin (Page 1, Paragraph 0004). Further to maximize patient comfort, Brimhall teaches that the wings be made of a soft, flexible material such as silicone (Page 1, Paragraph 0005). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the covering of Olsen in view of Wilson to have silicone wings as taught by Brimhall to facilitate taping or suturing of the catheter to the patient's skin and to maximize patient comfort.

13. Claim 16 differs from Olsen in calling for the body to have a non-uniform outer surface, and the winged portion to have a non-uniform inner surface. Wilson teaches that the cover fits axially about the catheter tube and it attachable by a non-uniform inner surface that meshes with a non-uniform outer surface of the catheter to securely attach the cover to the body (Page 7, Lines 18-21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Olsen to include a cover with a non-uniform inner surface that meshes with the non-uniform outer surface of the body as taught by Wilson to securely attach the cover to the body.

14. Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Belloti (EPO 0183396 A1). Claim 11 differs from Olsen in calling for the catheter receiving portion of the mating portion to funnel outward. Belloti teaches that the bore of the

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connector is funneled outward so that the bore does not engage the inserted cannula until it is advanced further into the connector (Page 3, lines 13-24). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector of Olsen to have a funneled end as taught by Belloti so that the cannula is not immediately engaged with the connector upon insertion.

15. Claim 20 differs from Olsen in calling for the mating portion to include catheter gripping liners. Belloti teaches a connector having a catheter gripping liner 48 that surround and protect the catheter when the mating portions are closed. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector of Olsen to have catheter gripping liners as taught by Belloti to surround and protect the catheter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura A Bouchelle
Examiner
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